(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 494 636 A1**

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **92100142.6**

(51) Int. Cl.5: **A61B 17/06**, B21F 15/06

(22) Date of filing: **07.01.92**

(30) Priority: **07.01.91 US 638195**

(43) Date of publication of application:
15.07.92 Bulletin 92/29

(84) Designated Contracting States:
BE CH DE ES FR GB IT LI LU NL SE

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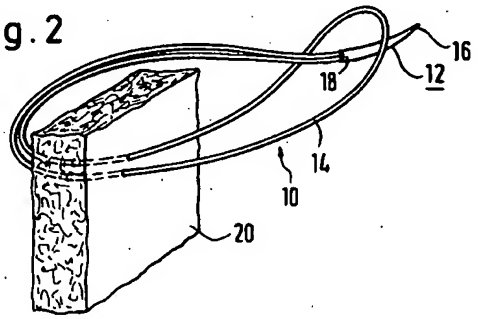
(54) Loop threaded combined surgical needle-suture device.

(57) A loop threated needle-suture device (10) is disclosed wherein a surgical needle (12) is provided with a pointed end (16) and a drilled aperture (22) extending axially of the butt end (18), and a length of flexible suture material (14) is doubled upon itself to form a loop, both free ends (24,26) of which are attached to the needle (12) in the butt end (18) aperture (22). The blunt end of the needle (18) is deformed to form the aperture (22) into an elliptical cross-section and the length of the loop is substantially greater than the length of the needle (18) to facilitate insertion of the needle (12) and suture material (14) into tissue (20) to be sutured, and looping the needle (12) through the suture material (14) prior to tieing the suture material (14). Thus, the loop funtions as a double suture. A method of forming the unique loop threaded needle-suture (10) is disclosed.

Fig.2



EP 0 494 636 A1

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a combined surgical needle-suture device and more particularly to a drilled needle-suture device in which a suture, in the form of a looped thread, is attached to the needle.

2. Description of the Prior Art

For many years, surgeons have employed needle-suture combinations in which a suture or ligature is attached to the shank end of a needle. Such needle-suture combinations are provided for a wide variety of monofilament and multifilament braided suture materials, both absorbable and non-absorbable, e.g., catgut, silk, nylon, polyester, polypropylene, linen, cotton, and absorbable synthetic materials such as polymers and copolymers of glycolic and lactic acids.

Needle-suture combinations generally fall into three classes: eyed, with no suture attached; drilled end, i.e. with an aperture bored down the long axis of the needle and a suture secured in the bore; and channeled, i.e. with a U-shaped recess or channel with an end of the suture secured in the channel. Examples of drilled and channeled needles are provided by U.S. Patent No. 3,534,740, while eyed needles are disclosed, for example, in U.S. Patent Nos. 1,960,117 and 4,182,341. The last mentioned '341 patent incorporates a relatively short loop of polymer strand to form the eye of the needle.

More recently, it has become increasingly desirable to reduce the time required to suture a wound or opening and to tie the suture satisfactorily. While threading the suture has become improved somewhat, the last mentioned objective of quickly tieing the suture has not been significantly improved. The present invention incorporates a looped suture into a surgical needle to facilitate quick knotting and tieing as needed during critical surgical procedures.

SUMMARY OF THE INVENTION

It has now been found that an improved loop threaded needle-suture device can be provided by employing a drilled needle in place of a channeled needle wherein the butt end of the needle is provided with a looped flexible suture attached within a substantially elliptical shaped bore. The loop functions as the actual suture material.

The invention relates to a looped suture device which comprises a needle having a pointed end and a butt end, the butt end having an aperture extending generally axially thereof and having a cross-sectional dimension greater in a first direction than the cross-sectional dimension substantially perpendicular to the first direction, a loop formed from a suture material and having both free ends positioned within the aperture and attached to the needle. The looped suture device may include a curved surgical needle or a straight needle manufactured of any surgically acceptable metal alloy such as 400 series surgical stainless steel.

By "Aperture" is meant an opening surrounded on all sides by material forming the butt end of the needle, as compared to a channel which is open on one side. With a channeled needle it would be difficult to insert and retain both suture ends into the channel during the swaging process. Further, swaging the open ends of the channel without surface irregularities presents a separate and distinct difficulty.

The suture material includes such suture materials as polypropylene, silk, nylon, linen, cotton, polyester, stainless steel, natural materials such as catgut, and synthetic polymers having glycolic acid ester linkages subject to hydrolytic degradation to non-toxic, tissue compatible absorbable components, including polyglycolic acid. Monofilament and multifilament materials may be used.

Initially a needle is provided having an oversized drilled aperture in the butt end. The butt end is swaged to form the aperture into an elliptical shape. After inserting the two free ends of the looped flexible suture material into the aperture, the butt end of the pointed needle is inwardly swaged in at least one direction to provide inward force directed at the flexible suture material to attach the suture material to the needle. Alternatively, dies requiring a single hit may be utilized.

The flexible suture material loop is of sufficient length to facilitate looping the needle through the loop to tie the suture after passing the needle and a portion of the loop through the body tissue.

Although the examples set forth hereinbelow are directed to standard needle suture attachments, the invention is nevertheless applicable to removable needle attachments. The minimum acceptable forces required to separate a needle from a suture are set forth for various suture sizes in the United States Pharmacopeia ("USP"). For example, the USP prescribes minimum individual pull-out forces and minimum average pull-out forces as measured for various representative needle-suture combinations for both standard and removable needle/suture attachments. The minimum acceptable pull-out forces for both standard and removable needle-suture attachments set forth in the USP are hereby incorporated by reference. However, in practicing the present invention, the pull-out force for both standard and detachable sutures should be comparable to the stated pull out force

for a single strand of the same size suture. Thus, the closure of the butt end of the needle with respect to the doubled or "end to end" suture portions positioned within the butt end of the needle as disclosed herein can be modified appropriately by persons skilled in the art to accomplish the same attachment (in Kgf) as with a single strand positioned in the needle butt end. Examples of the present invention are set forth hereinbelow for relatively large size suture strands having standard needle/suture attachments of about 2.10 (Kgf). For the size suture strand used, this attachment force is slightly greater than the average force set forth in the USP Examples. Accordingly, some variations of this force with the suture size listed are permissible within the scope of the invention.

The looped suture device includes a flexible suture loop of length sufficient to permit insertion of the needle into body tissue to be sutured and thereafter, reversing the direction of the needle and inserting it into the loop to facilitate tieing or knotting the suture prior to releasing the suture from the needle. Essentially, the provision of an elliptical opening at the butt end of the needle facilitates insertion and attachment of the loop of suture material to the needle aperture with the free ends of the suture material in adjacent engaged relation in the elliptical aperture. However, broadly any aperture having a major dimension and a lesser minor dimension transverse to the major dimension is contemplated. The loop is preferably at least 60 inches in total length, doubled to form a loop of 30 inches.

A method is disclosed for manufacturing a looped suture device which comprises taking a surgical needle having a pointed end and a butt end, the butt end having an aperture extending axially thereof and of predetermined length, providing a flexible suture material and looping the suture material such that the two free ends thereof are in adjacent engaged side-to-side relation. The method comprises deforming the but end such that the aperture assumes a cross-sectional shape having a major dimension greater in length than a minor dimension substantially perpendicular to the major dimension. The aperture of the needle is dimensioned sufficient to receive a predetermined length of the free end portions of the flexible suture material while maintaining the free end portions in the end to end relation. According to the method at least one inwardly directed force is provided on the butt end of the needle to cause the needle material to become inwardly swaged sufficient to provide inward predetermined attachment force on the suture material. With standard needle suture dies requiring at least two hits, the second and subsequent inwardly directed forces are provided on the butt end of the needle in directions generally perpendicular to the provided force to thereby cause the needle material to become further swaged to provide predetermined attachment force on the flexible suture material.

Particular improved dies are disclosed in EP-A-426377 and 426378.

With such improved dies, a single hit may be used to attach the needle and the looped suture material.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described hereinbelow with reference to the drawings wherein:

Fig. 1 is a perspective view of a looped suture device constructed according to the invention;

Fig. 2 is a perspective view of the looped suture device of Fig. 1 inserted into body tissue and looped upon itself;

Fig. 3 is a plan view, partially in cross-section, and partially broken away, of the looped suture device shown in Fig. 1;

Fig. 4 is a cross-sectional view of a drilled needle butt end prior to forming the aperture into an elliptical shape;

Fig. 5 is a cross-sectional view of the drilled needle butt end shown in Fig. 4 after partially compressing the butt end such that the aperture assumes an elliptical shape;

Fig. 6 is a cross-sectional view of the drilled needle butt end of Fig. 5 with the free ends of the looped suture inserted into the elliptical aperture prior to swaging; and

Fig. 7 is a cross-sectional view taken along lines 7-7 of Fig. 3, of the needle butt end of Fig. 6 after the needle/suture loop attachment is completed by swaging the butt end of the needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Fig. 1 the looped suture device 10 constructed according to the present invention is illustrated. The looped suture device is formed of surgical needle 12 attached to flexible suture material 14 as shown. The needle is preferably constructed of a suitable surgical steel such as surgical stainless steel and has pointed end 16 and butt end 18. Such materials as 300 and 400 series surgical stainless steel are contemplated. However, any suitable surgically approved metal alloy may be used. The actual suture is in the form of a loop.

Referring now to Fig. 2, a significant feature of the looped suture device is illustrated. The needle 12 is inserted into a portion of body tissue (illustrated schematically at 20). Thereafter, the su-

ture device may be conveniently looped upon itself as shown, by inserting the pointed end of the needle into the looped suture material 14 and forming an appropriate tie or knot to secure the device with respect to the tissue. Tieing or knotting may not be required if the suture is being applied only for the purpose of restraining tissue during a surgical procedure.

In Fig. 3, the looped flexible suture material 14 is illustrated with portions broken away, with both free ends 24, 26 positioned in adjacent end to end relation within an elongated elliptical aperture which extends axially of the butt end 18 of the needle. The needle is shown greatly enlarged in Fig. 3 for illustrative purposes. The cross-sectional view shown in Fig. 4 illustrates the attachment.

The present invention may be utilized in numerous applications including 1) starting a continuous stitch by tieing a knot with the flexible suture material; 2) restraining tissue temporarily during a surgical procedure; 3) inserting the suture device with the flexible portion partially into the tissue and tieing a knot. Clearly, other applications will readily come to the mind of a person skilled in the art.

The preferred method of attaching the flexible suture material 14 to the butt end 18 of the needle 12 is best illustrated by Figs. 4-7. Needle 12 is initially provided with an oversized drilled aperture 22 extending axially of the butt end and having a predetermined length as shown in Fig. 3. The aperture is surrounded on all sides by the material forming the needle butt as shown in Fig. 4. Moreover, the expression "drilled aperture" contemplates a needle drilled by mechanical means, laser or the like. However, any needle having an elongated aperture as described is contemplated, regardless of how the aperture is formed in the butt end of the needle. The initial aperture is oversized with respect to the size of the flexible suture material, i.e., capable of freely receiving both free ends loosely. The butt end of the needle is first compressed inwardly using a reduced swaging pressure with an appropriate die or tool to cause the butt end 18 to assume an elliptical cross-section as show in Fig. 5. Both free ends 24, 26 of the suture material are placed in end to end contacting relation as shown and inserted into the now elliptical aperture as shown in Fig. 6. Alternatively, a needle having a substantially elliptical opening may be provided in the first instance.

In certain applications it may be desirable to treat the ends of the suture material with a suitable tipping agent such as a cyanoacrylate. Most notable of such instances is where the suture material has a tendency to become limp or where a multifilament material is subject to a brooming effect. Thereafter, the butt end of the needle is subjected to inward force by suitable dies to cause the butt end to crimp so as to complete the attachment of the needle to the flexible suture material.

The attachment process may be accomplished by standard dies utilized for surgical needle/suture attachments utilizing a lap-overlap swaging die at a reduced swaging pressure, whereby the bore may be swaged under standard conditions to secure the flexible material to the needle as shown in Fig. 7. A "double hit" technique may be used whereby the needle suture attachment is accomplished by sequential hits along mutually perpendicular directions. Depending upon the intended application, any number of multiple hits may be used, rotating the direction of hit with respect to the needle 90 degrees between hits.

Alternatively, the attachment may be accomplished utilizing such apparatus as disclosed in commonly assigned EP-A-0426377 and EP-A-426378. Both of the last mentioned applications are incorporated by reference herein and made a part of this disclosure. In either case, with such improved devices as disclosed in the aforementioned applications, the needle will be swaged by a single hit as disclosed in these applications.

Also, the swaging action may be carefully and precisely controlled to provide for controlled release of the needle from the suture material by predetermined forces after the suture attachment on the body tissue is completed.

The present invention combines a surgical needle with a looped suture material wherein the length of the loop is substantially greater than the length of the needle to facilitate tieing the suture material in a knot or other tie. Thus, the combination of the attachment disclosed herein and the unique relatively lengthy suture loop material form significant features of the invention. Further, any type of surgical needle is contemplated, including curved needles, straight needles, etc., of various alternative surgically approved materials.

Examples of typical combined looped devices as disclosed herein and attached by double hit techniques are as follows:

EXAMPLE 1

1. Surgical stainless steel needle
2. Needle type: half inch taper point
3. Wire size O.D. 0.062"
4. Aperture size I.D. Unswaged: 0.035-0.0365"
5. Monofilament size #1 Polypropylene 60" loop, doubled to 30" length
6. Needle elliptical aperture, major dimension .066"; minor dimension range: 0.038-0.042"
7. Swaging conditions: lap overlap conventional die: 0.062"
8. Long land width of die: 0.045" (range 0.040-0.060")

- Corresponds to depth of aperture -
9. Machine pressure: 40 to 60 PSI
10. Hits required to produce minimum holding force of 2.10 kg = two to three hits, turning needle 90° after each swage.

EXAMPLE 2

1. Surgical stainless steel needle
2. Needle Type: Half inch taper point
3. Wire Size: O.D. 0.062
4. Aperture Size: I.D. Unswaged 0.040-0.0415"
5. Needle Elliptical Aperture
Major dimension 0.070"
Minor dimension range: 0.030-.0365"
6. Polypropylene size #2, 60" loop doubled to 30" length
7. Swaging conditions: lap overlap conventional die .062"
8. Long land width of die: 0.045" (range 0.040-0.060")
- Corresponds to length of aperture -
9. Machine pressure: 40 to 60 PSI
10. Hits required to produce minimum holding force of 2.10 kg = two to three hits, turning needle 90° after each swage.

EXAMPLE 3

1. Surgical stainless steel needle
2. Needle Type: Half inch taper point
3. Wire Size: O.D. 0.062
4. Aperture Size: I.D. Unswaged 0.040-0.0415"
5. Needle Elliptical Aperture
Major dimension 0.070"
Minor dimension range: 0.030-.0365"
6. Braided Synthetic Absorbable suture size #1, 60" loop doubled to 30" length
7. Swaging conditions: lap overlap conventional die .062"
8. Long land width of die: 0.045" (range 0.040-0.060")
- Corresponds to length of aperture -
9. Machine pressure: 40 to 60 PSI
10. Hits required to produce minimum holding force of 2.10 kg = two to three hits, turning needle 90° after each swage.

Preferred suture materials include absorbable or non-absorbable, natural or synthetic monofilament, multifilament or braided suture materials. Preferred suture materials include monofilament polypropylene and synthetic polymers having glycolic acid ester linkages subject to hydrolytic degradation to non-toxic, tissue compatible absorbable components including polyglycolic acid, multifilament braided sutures or the like. Other suture materials contemplated include silk, nylon, linen, cotton, polyester, stainless steel, and natural materials such as catgut.

Claims

1. A looped suture device which comprises a needle having a pointed end and a butt end, said butt end having an aperture extending generally axially thereof and having a cross-sectional dimension greater in a first direction than the cross-sectional dimension substantially perpendicular to said first direction, and a loop formed from a flexible suture material and having both free ends positioned within said aperture and attached to said needle.

2. A device as claimed in claim 1 wherein said flexible suture material has a generally circular cross-sectional configuration.

3. A device as claimed in claim 1 or 2, wherein said loop is of length substantially greater than the length of said needle to facilitate insertion of said needle and at least a portion of said flexible suture material into tissue to be sutured and insertion of said needle into said loop.

4. A device as claimed in claim 3 wherein said looped suture material is at least 150 cms (60 inches) in length, doubled to a 75 cm (30 inch) loop length.

5. A device as claimed in any one of the preceding claims, wherein said needle is a surgical needle.

6. A device as claimed in any one of the preceding claims, wherein said needle has an arcuate configuration.

7. A device as claimed in any one of the preceding claims, wherein said needle is manufactured of 400 series surgical stainless steel.

8. A device as claimed in any one of the preceding claims, wherein said elongated aperture has a substantially elliptical cross-sectional configuration.

9. A device as claimed in any one of the preceding claims, wherein said suture material is a synthetic polymer having glycolic acid ester linkages subject to hydrolytic degradation to non-toxic, tissue compatible absorbable components.

10. A device as claimed in any one of the preceding claims, wherein said butt end of said pointed needle is inwardly swaged in at least two

directions to provide inward forces directed at said flexible suture material to attach said suture material to said needle.

11. A device as claimed in any one of the preceding claims, wherein the suture material is attached to said needle at said butt end of said needle in a way which provides a predetermined pull-out force to pull said flexible suture material out of said needle.

12. A device as claimed in claim 11 wherein said pull-out force is, on average, approximately 2.10 kilogram-force.

13. A device as claimed in any one of the preceding claims, for use in a method of suturing body tissue which comprises the steps of inserting said needle into the body tissue until at least a portion of said suture material penetrates the body tissue, substantially reversing the direction of said needle and inserting said needle through said looped suture material.

14. A method of manufacturing a looped suture device which comprises:

a) taking a surgical needle having a pointed end and a butt end, said butt end having an aperture extending axially thereof and of predetermined length;

b) providing a flexible suture material and looping said suture material such that the two free ends thereof are in adjacent engaged end to end relation:

c) forming at said aperture with a cross-sectional shape having a major dimension greater in length than a minor dimension substantially perpendicular to said major dimension, said aperture of said needle being dimesioned sufficient to receive a predetermined length of said free end portions of said flexible suture material while maintaining said free end portions in said end to end relation;

d) inserting a predetermined length of said free end portions of said suture material into said aperture while maintaining said free end portions in end to end relation; and

e) providing at least one inwardly directed force on said butt end of said needle to cause said needle material to become inwardly swaged sufficient to provide inward predetermined attachment force on said suture material.

15. A method according to claim 14 wherein the forming step is accomplished by deforming the butt end of the needle.

16. A method according to claim 15 wherein the deforming step is by swaging.

17. A method according to any one of the claims 14, 15 and 16, which comprises the further step of: i) positioning a pair of dies about said butt end of said needle, the dies serving to provide said inwardly directed force; and ii) applying inward force to said dies to cause said des to strike said needle butt end to transmit inwsrd criping forces thereto so as to attach said flexible suture material to said needle.

18. A method according to claim 17, wherein each die has a pair of inner arcuate surface portions spaced apart from each other to provide a material relief zone, whereby portions of material forming part of said butt end to be deformed can collect within relief zones between said pairs of arcuate surface portions.

19. A method according to claim 17, wherein each die has a generally arcuate undulating surface portion facing said butt end and including concave portions, whereby deformed material of said butt end can collect within said concave portions so as to avoid distortion of said butt end.

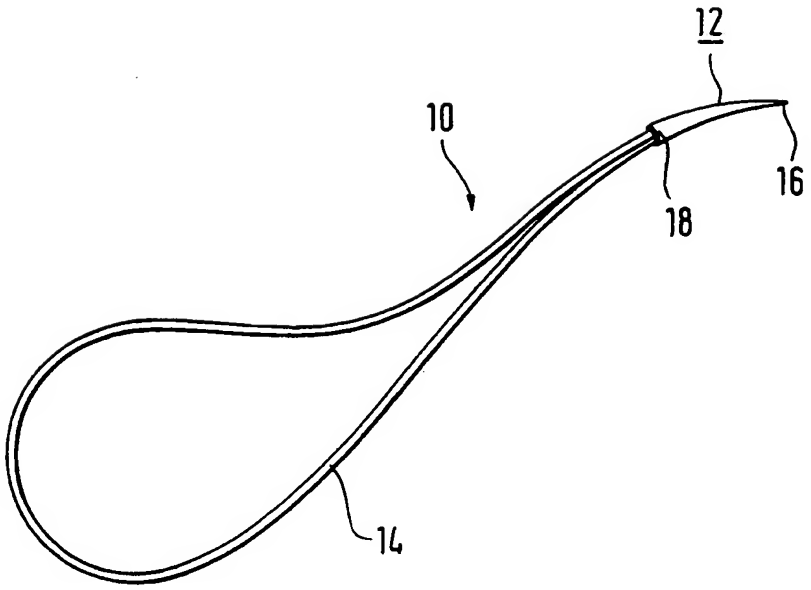
20. A method according to any one of claims 14 to 19 wherein said flexible suture material has a generally circular cross-sectional configuration.

21. A method according to any one of claims 14 to 20 further comprising treating the free end portions of said flexible suture material with a tipping agent prior to positioning said free end portions within said aperture of said needle.

22. A method according to claim 21 wherein said tipping agent is a cyanoacrylate.

23. A method according to any one of claims 14 to 22, further comprising providing at least a second inwardly directed force on said butt end of said needle in a direction generally perpendicular to said first inwardly-directed force, thereby to cause said needle material to become further swaged to provide predetermined attachment force on said flexible suture material.

Fig.1



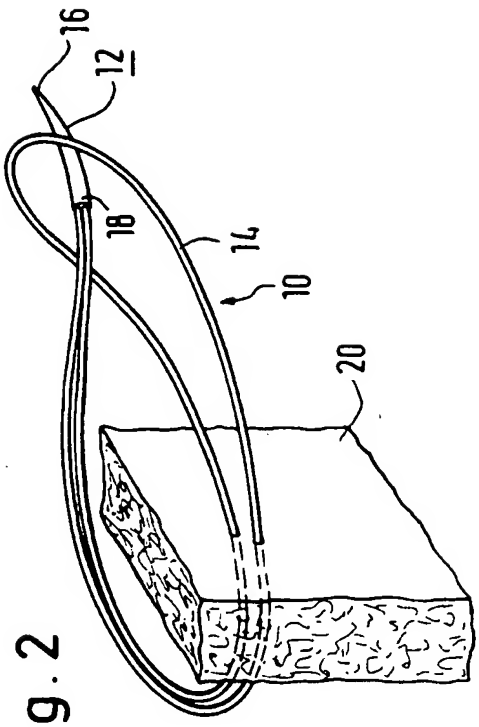


Fig. 2

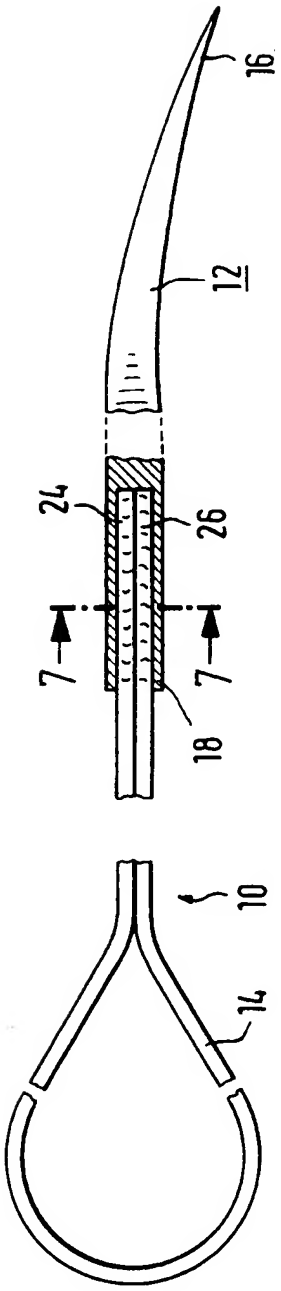


Fig. 3

Fig.4

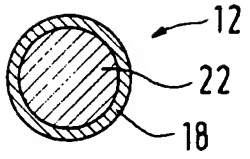


Fig.5

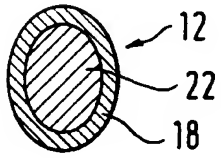


Fig.6

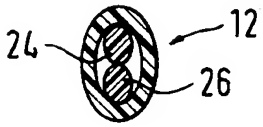


Fig.7

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PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 92 10 0142

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y,D	US-A-4 182 341 (PERRI) * Column 2, lines 15-57; column 3, line 25 - column 4, line 12; claims 1-5; figures 1-3 *	1,2,5,6,8,10,11,14-17,20,23	A 61 B 17/06 B 21 F 15/06
A	---	7,9	
Y	US-A-3 924 630 (WALLDORF) * Column 4, lines 8-28; claim 1; figures *	1,2,5,6,8,10,11,14-17,20,23	
A	---	7,12	
A	US-A-4 932 962 (YOON) * Column 5, lines 53-56; column 7, lines 16-58; figures 5,8,9 *	1-3	
A	---	1,3	
	US-A-4 950 285 (WILK) * Abstract; figures * --- -/-		

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B
B 21 F

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely: 1-12,14-23

Claims searched incompletely:

Claims not searched: 13

Reason for the limitation of the search:

The looped suture device according to claim 13 is only defined as being suitable for use in a certain surgical method.
No technical features to be searched (obscurity)

Place of search	Date of completion of the search	Examiner
THE HAGUE	10-04-1992	KLEIN C.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P0407)

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PARTIAL EUROPEAN SEARCH REPORT

Application Number EP 92 10 0142

	Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
1	A	US-A-4 060 885 (HOFFMAN) * Column 6, lines 19-58; column 8, line 17 - column 11, line 18; figures *	1,2,5-12,14-17,20,23
1	A,P D	EP-A-0 426 378 (U.S.S.C.) * The entire document *	1,2,5-12,14-18,20,23
5	A	US-A-2 983 898 (KALMAR) * Column 4, lines 19-22,29-44,49-53; figures 1,10,11 *	18
1	A,P D	EP-A-0 426 377 (U.S.S.C.) * The entire document *	1,2,5-12,14-17,19,20,23
3	A	GB-A-1 526 222 (CCL SYSTEMS) * Page 1, line 62 - page 2, line 4; figures *	19
1	A	FR-A-2 356 404 (ETHICON) * Claim 1; figures *	21
3	A	EP-A-0 040 187 (ROHLAND)	

CLASSIFICATION OF THE APPLICATION (Int. Cl.5)

TECHNICAL FIELDS SEARCHED (Int. Cl.5)